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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,288	02/26/2002	Anthony C. Vrba	1001.1541101	4123
28075	7590	06/08/2005		EXAMINER
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SA

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/083,288	VRBA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 May 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-27 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Objections***

1. Claim 16 is objected to because of the following informalities: The claim contains a registered trademark of DuPont, "Dacron", which cannot be claimed. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-10 and 17-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Levinson et al (6,277,139).

Levinson et al disclose a vascular protection and embolic material retriever and further disclose an elongated core wire having a longitudinal axis, a proximal end and a distal end; an actuatable stop (20) disposed at the distal end of the core wire, the actuatable stop (20) moveable between a collapsed position and an expanded position; an actuator couple to the stop (20), the actuator moveable between a first position and a second position to move the stop (20) between the collapsed position and the expanded position; a filter disposed on the core wire; the actuatable stop (20) comprises a tubular member having a proximal end and a distal end; the distal section of said tubular

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member includes a plurality of circumferentially disposed openings adapted to permit a plurality of struts disposed therebetween to expand in an outward direction; the inner diameter of the tubular member is substantially similar to the outer diameter of the core wire; the inner diameter of the tubular member is larger than the outer diameter of the core wire; a locking mechanism adapted to prevent relative motion between the actuatable stop (20) and the core wire; the locking mechanism comprises an enlarged outer diameter portion disposed on the core wire; the locking mechanism comprises an enlarged outer diameter portion disposed on the core wire corresponding in size and shape to a reduced inner diameter portion disposed on the actuatable stop (20); the locking mechanism comprises a locking hub disposed about a proximal portion of the core wire; and an actuator disposable about the core wire, the actuator having a proximal end and a distal end. See Column 6, lines 21-37; Column 7, lines 31-67; Column 9, lines 47-53; Column 12-20; Column 12, lines 48-51; and Column 13, lines 33-36.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levinson et al (6,277,139) as applied to claim 10 above, and further in view of Dubrul et al (6,602,265).

Levinson et al, as discussed above, disclose a vascular protection and embolic material remover but fail to disclose the actuatable stop comprises a polymeric tube; the actuatable stop comprises a mesh sleeve; and the mesh sleeve comprises Dacron. Dubrul et al, as discussed above disclose an intravascular tissue separation device and further disclose the actuatable stop comprises a polymeric tube; the actuatable stop comprises a mesh sleeve; and the mesh sleeve comprises Dacron. See Column 7, lines 15-23 and 51-67; Column 8, lines 13-15; and Column 14, lines 1-8 and 44-54.

Since both Levinson et al and Dubrul et al disclose intravascular devices that remove material, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Levinson et al to include the use of a polymeric tube or a polymeric mesh sleeve, as per the teachings of Dubrul et al, since it is well known in the art to utilize many biocompatible materials on intravascular devices, including metals as well as polymeric materials.

6. Claims 11, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levinson et al (6,277,139) as applied to claim 10 above, and further in view of Tate (3,841,308).

Levinson et al, as discussed above, disclose a vascular protection and embolic material retriever but fail to disclose the actuatable stop comprising a spring coil; a spring coil helically disposed about the core wire; and the polymeric tube is accordion-shaped.

Tate discloses a distally valved catheter device and further discloses the actuatable stop comprising a spring coil; a spring coil helically disposed about the core wire; and the polymeric tube is accordion-shaped. See Figures 2, 4 and 6-8.

Since both Levinson et al and Tate disclose catheter devices, it would have been obvious to one of ordinary skill in the art to modify the device of Levinson et al to include the use of a spring coil and have the polymeric tube be accordion-shaped, as per the teachings of Tate, since it is well known to provide a helical coil about the distal end of a guidewire device as well as a polymeric tube that has the ability to be accordion-shaped.

7. Claims 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al (5,167,239) in view of Dubrul et al (6,602,256 B2).

Cohen et al disclose an anchorable guidewire and further disclose advancing a catheter along the guidewire; providing an articulating guidewire comprising an elongated core wire having a longitudinal axis, a proximal end and a distal end; and an actuatable stop disposed at the distal end of the core wire, said actuatable stop moveable between a collapsed position and an expanded position; inserting the guidewire into the lumen of a blood vessel; positioning a distal portion of the guidewire beyond a lesion or other protrusion within the body; actuating the actuatable stop from the collapsed position to the expanded position; and the actuator is coupled to the actuatable stop. See Column 3, lines 64-68; Column 14, lines 31-68; and Column 15, lines 1-8.

Cohen et al however fail to disclose advancing a filter on the guidewire; and advancing an intravascular device along the core wire until the intravascular device abuts the outwardly expanded stop.

Dubrul et al disclose a vascular protection and embolic material retriever placed over a guidewire and further disclose advancing a filter on the guidewire; and advancing an intravascular device along the core wire until the intravascular device abuts the outwardly expanded stop. See Column 6, lines 63-64; Column 7, lines 15-23 and 51-67; Column 8, lines 13-15; and Column 14, lines 1-8 and 44-54.

Since both Cohen et al and Dubrul et al disclose the advancement of catheters along a guidewire, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Cohen et al to include the use of a filter, as per the teachings of Dubrul et al, since it would provide a means of trapping and removing material from within the lumen.

#### ***Response to Arguments***

8. Applicant's arguments filed May 10, 2005 have been fully considered but they are not persuasive. Regarding claim 16, the use of Dacron remains objected due to the fact that Dacron is a registered trademark of the DuPont Corporation. Dacron is not considered a "name used in the trade" as disclosed in the MPEP § 608.01(v). The objection will stand until the claim is cancelled or Dacron is replaced with a generic name. Furthermore, the Examiner has consulted with his Supervisor about the use of

trademarks in claims, and the Supervisor has relayed to the Examiner that the Group Director has reaffirmed the use of Trademarks in claims is prohibited, per the MPEP.

The Examiner respectfully traverses the argument that the interpretation of the claims is not reasonable in light of the specification, and therefore Levinson et al fails to disclose the claimed elements. Per the current disclosure, a stop is moveable between a collapsed position and an expanded position. In Levinson et al, the expandable frame (20) acts in a similar manner to that of the claimed stop, wherein the frame is moveable between a collapsed position and an expanded position. Therefore, since Levinson et al discloses a stop that operates in a manner similar to that of the current claim language and disclosure, Levinson et al clearly discloses an actuateable stop (20). With regards to the filter of the current claims, the filter has not been claimed in a manner that would lead one of ordinary skill in the art to come to the conclusion that the filter is a separate element that is slidably disposed on the guidewire until it comes in contact with the claimed stop.

9. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Dubrul et al

disclose TRAP (13) that acts in a manner similar to that of the anchoring guidewire of Cohen et al, in particular, expanding until the element contacts the blood vessel wall.

10. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BS

  
MAX F. HINDENBURG  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700